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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,916	06/27/2001	Donald R. Ricci	213202.00271	8554

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EXAMINER	
SNOW, BRUCE EDWARD	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 08/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,916	RICCI ET AL.	
	Examiner	Art Unit	
	Bruce E. Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments 5/12/05 have been fully considered but are not persuasive.

Regarding the objection to the drawings, "[t]he drawings must show every feature of the invention specified in the claims". Applicant states, "[a]pplicants respectfully submit that the person of ordinary skill in the field readily understands the structure "a porous surface defined by a plurality of interconnecting struts"". The Examiner stated in the Final Office action, dated 5/8/03, *"[t]he claimed limitation, "a porous surface defined by a plurality of interconnecting struts" is not understood by one having ordinary skill in the art; the language "porous surface" is know in the art as simply having pores in the surface which do not extend all the way through the walls as compared with the struts which form openings all the way through the walls."* The Examiner strongly believes drawings of this claimed subject matter would help define the limitation to one skilled in the art.

Regarding claims 32-47 and 55-58 are rejected under 35 U.S.C. 102(b) as clearly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Prior Art as defined in applicant's specification including at least page 5, lines 12 et seq.

MPEP 2129 states:

2129 Admissions as Prior Art [R-2]

I. <ADMISSIONS BY APPLICANT CONSTITUTE PRIOR ART

**>A statement by an applicant during prosecution identifying the work of another as "prior art" is an admission that that work is available as prior art against the claims, regardless of whether the admitted prior art would

> otherwise qualify as prior art under the statutory categories of 35 U.S.C. 102. *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1354, 66 USPQ2d 1331, 1337 (Fed Cir. 2003).

The Examiner believes that applicant's "Background Art" is an admission that the work is by another and is prior art. The rejected was labeled as being "clearly anticipated by" meaning one having ordinary skill in the art should be able to interpret claimed limitations in the admitted prior background art; limitations such a stent having a proximal end, distal end, and a wall with a longitudinal axis as required by applicant's first independent claim 32 are self-evident. Note that applicant's examples of the prior art, the listing starting on page 2 of the specification, are fully incorporated therein.

It is the Examiner's position that "about 4 mm" admitted by applicant as being known in the art fulfills the claim language of "about 3.5 mm". Applicant's claimed invention is a stent that has a maximum yield point at about 3.5 mm versus at about 4 mm, a difference of only about 0.5 mm!

In the alternative, under 35 U.S.C. 103(a) as obvious over the Prior Art

It is the Examiner's position that it would have been an obvious matter of design choice to have made a smaller diameter stent in the claimed range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

It is the Examiner's position that it would have been obvious to one having ordinary skill in the art to have made a smaller diameter stent such that it has a maximum diameter correlating to the maximum yield point which is less than or equal to

about 3.5 mm such that the stent could be used in smaller patients, children, or simply smaller vessels.

Applicant's argues that a smaller diameter stent would not have to have a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm, and that there are many structural features beside diameter which affect the maximum yield point. It is the Examiner's position that a smaller stent, one having a smaller diameter, has less material circumferentially which inherently would reach a maximum yield point earlier. It is obvious to make various sized stents which are less than about 4.0mm. Additionally, applicant's definition of "maximum yield point" and "less than or equal to about 3.5 mm" are both very broad. Applicant admits that it is known in the art that it is generally desirable to deploy the stent to a diameter at about its maximum yield point (page 4, lines 25 et seq.). Obviously this would be true for when making a smaller stent. It is the Examiner's position that making a smaller stent for a smaller situation is not patentable.

The Examiner's position regarding the rejections in Alt et al (5,843,117) are clearly stated in the grounds of rejection.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "a porous surface defined by a plurality of interconnecting struts" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-47 and 44-58 are rejected under 35 U.S.C. 102(b) as clearly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the Prior Art as defined in applicant's specification including at least page 5, lines 12 et seq.

Applicant's specification teaches: **"[f]or most conventional stents the maximum yield point is reached at a point when the diameter of the expanded stent is about 4 mm to about 5 mm**."

It is the Examiner Examiners position that "about 4 mm" fulfills the claim language of "about 3.5 mm" and even including "about 3.0 mm" as claimed in claim 44.

Regarding any of the specific stent limitations such as "porous surface defined by a plurality of interconnecting struts", coatings, etc., catheters, crimping steps, these limitations are well know in the art and taught in applicant's examples of the prior art, the listing starting on page 2 of the specification.

Regarding applicant claiming, for example claim 33, "*a first unexpanded position," "second pre-expanded position," "third expanded position",* this is merely functional language in which all the prior art stents are fully capable of performing. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the structural limitations of that claimed.

Regarding claim 41, an expanded stent as taught in the prior art inherently is expanded through a pre-expanded position before being expanded to its maximum yield point.

In the alternative, under 35 U.S.C. 103(a) as obvious over the Prior Art

If "about 4 mm" does not fulfill the claim language of "about 3.5 mm" to "about 3.0 mm": It would have been an obvious matter of design choice to have made a smaller diameter stent in the claimed range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Additionally, it would have been obvious to one having ordinary skill in the art to have made a smaller diameter stent such that it has a maximum diameter correlating to the maximum yield point which is less than or equal to about 3.5 mm such that the stent could be used in smaller patients, children, or simply smaller vessels.

Claims 32-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al (5,843,117).

Alt et al teaches a stent having a distal end and proximal end with a tubular wall disposed there between. Said wall having a plurality of interconnecting struts defining apertures (pores). Alt et al further teaches a fully deployed diameter *"from about 2.5 to about 5.0 mm"*; see column 16, lines 54-65. The fully deployed diameter (5.0 mm of Alt et al) is well known in the art to correspond to approximately the maximum yield point of the stent. (Applicant's specification teaches *"in conventional stents.. it is generally desirable to deploy the stent to a diameter which is as close as possible to, but does not exceed, the maximum yield point."* See applicant's specification page 4, lines 25 et seq.)

It would have been an obvious matter of design choice to have made a smaller diameter stent in the claimed range, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Additionally, it would have been obvious to one having ordinary skill in the art to have made a smaller diameter stent such that it has a maximum diameter correlating to the maximum yield point which is less than or equal to about 3.5 mm such that the stent could be used in smaller patients, children, or simply smaller vessels.

Regarding applicant claiming, for example claim 33, "*a first unexpanded position," "second pre-expanded position," "third expanded position",* this is merely functional language in which the stent of Alt et al is fully capable of performing. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from the prior art apparatus satisfying the structural limitations of that claimed. The device disclosed by Alt et al fulfills the metes and bounds of the claim specified by the applicant and is fully capable of the performing the intended function. Additionally, Alt et al teaches a "pre-expanded position" (termed partial expansion or pre-opening); see column 8, lines 17 et seq. and column 15, lines 39 et seq.

Regarding claim 34, Alt et al teaches 2.0 to 2.3 mm. See column 15, line 58.

Regarding the first unexpanded position having a diameter of less than or equal to about 1.1 mm, Alt et al teaches about 1.6 mm **as an example**. It is the Examiner

position that "about 1.6 mm" meets the claim limitation of "about 1.0 mm". Further, 1.6 mm diameter is only an example is believed to correspond to the a fully expanded diameter of 5-6 mm. Inherently, a stent having a fully expanded diameter of about 2.5 mm would have a first unexpanded diameter of about 0.5 to 1.0 mm.

Regarding claim 41, "A partially expanded stent," the device of Alt et al inherently can be "partially expanded stent" and does have a pre-expanded position as described above.

Regarding claims 45-55, see column 4, lines 17-30; column 4, lines 52-67; column 16, lines 54 et seq. Regarding claims 49-53 claiming a "mandrel" or "die"; Alt et al teaches a "needle" interpreted as the same device.

Claims 56-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al (5,843,117).

Alt et al teaches the stent as described above, however, is unclear as having a medicinal coating on the wall. Medicinal coatings on stents are well known in the art and would have been obvious to one having ordinary skill to have used any know coatings on the stent of Alt et al for improved acceptance by the body, etc.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

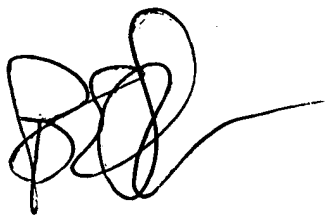
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

bes
July 27, 2005



BRUCE SNOW
PRIMARY EXAMINER